Practitioner's Docket No. <u>U 014690-3</u>

**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application	
of	
Iı	nventor(s)
for	
	of invention
	OR
In re application of: Buchi Reddy REGURI, et	
Serial No.: 10/601,282	Group No.:
Filed: June 20, 2003	Examiner:
For: NOVEL CRYSTALLINE FORMS	OF 11-CYCLOPROPYL-5,
11-DIHYDRO-4-METHYL-6H-DIPYRID	O [3,2-B: 2',3'-E][1,4]DIAZEPIN-6-ONE
(NEVIRAPINE)	-
Commissioner for Patents	
P. O. Box 1450	
Alexandria, VA 22313-1450	
TRANSMITTAL OF INFORM	IATION DISCLOSURE STATEMENT
WITHIN THREE I	MONTHS OF FILING OR
BEFORE MAILING OF FIRST	TOFFICE ACTION (37 C.F.R. 1.97(b))
CERTIFICATION UN	DER 37 C.F.R. 1.8(a) and 1.10*
	Express Mail label number is mandatory;
	certification is optional.)
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Dryg4	Signature
Date:	JANET I. CORD
	(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b): (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date. (2) Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date. (3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date. (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. (5) Each publication listed in an information disclosure statement must be identified by publisher, author (fi any), title, relevant pages of the publication, date, and place of publication. **WARNING:** No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37

C.F.R. § 1.97(f).

NOTE: The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).

## IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

- NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."
- NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuationsin-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

SIGNATURE OF PRACTITIONER

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JANET I. CORD

(type or print name of practitioner)

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Buchi Reddy REGURI, et al

Serial No.: 10/601,282

Group No. - -

Filed: June 20, 2003

Examiner: - -

NOVEL CRYSTALLINE FORMS OF 11-CYCLOPROPYL-5,

11-DIHYDRO-4-METHYL-6H-DIPYRIDO [3,2-B: 2',3'-E][1,4]DIAZEPIN-6-ONE

(NEVIRAPINE)

Attorney Docket No.: U 014690-3

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached references which are also listed

on the attached Form PTO-1449.

Respectfully submitted,

Janet I. Cord

C/O LADAS AND PARRY 26 WEST 61ST STREET NEW YORK, NY 10023

REG. NO. 33,778 (212) 708-1935

#### CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*

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"Since the filing of correspondence under  $\S$  1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

FORM PTO-1449

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## U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

applicant.

(Use several sheets if necessary)

	ATTY. DOCKET NO.	SERIAL NO.			
ĺ	U 014690-3	10/601,282			
APPLICANT  Buchi Reddy REGURI, et al					
ı	June 20, 2003				

RE	FEREN	ICE DESIGNATION	U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS		O DATE OPRIATE		
	АА	5,532,358	7/1996	Kelly	540	495				
_	АВ	5,569,760	10/1996	Schneider, et al	540	495		-		
	AC	5,366,972	11/1994	Hargrave, et al	514	220				
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				COUNTRY	CLASS	CLASS	YES	NO		
	AL	0 482 481	4/1992	EP						
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citation if not in conformance and not considered. Include copy of this form with next communication to